

Applicant(s): P. Bonutti  
Application No.: 09/925,551  
Examiner: V. Bui

### Remarks

Claims 72, 73, and 76-108 are pending in the application and are presented for the Examiner's review and consideration. Claims 72, 73, 77-89, and 91 have been amended and claims 71, 74, and 75 have been cancelled. Applicant believes the claim amendments, cancellations, and accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

### Interview Summary

The Applicant, through Applicant's attorney, held a telephonic interview with Examiner Vy Q. Bui on October 7, 2004. Applicant appreciates the courtesies extended to Seth Blum during this interview. The Examiner stated that in view of Applicant's arguments, the final rejection of claim 91 would require additional review. The Examiner also indicated that claim 91 as presented herein distinguishes over the prior art and would be considered favorably.

Accordingly, Applicant respectfully submits that the amendments and remarks presented herein reflect those discussed during the interview.

### Allowed Claims

Applicant acknowledges with appreciation the indication that claims 76 and 96 are in condition of allowance.

### 35 U.S.C. §102(e) and §103(a)-McGuire.

Claims 71-75, 79-80, 82-85, 87-92, 94-95, 99-100, 102-105, and 107-108 were rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 5,865,834 to McGuire. ("McGuire"). Claims 77-78, 81, 86, 93, 97-98, 101, and 106 were rejected under 35 U.S.C. §103(a) as unpatentable over McGuire.

Claims 71, 74, and 75 have been cancelled, rendering the rejection of these claims moot.

Claims 72, 73, and 77-90 have been amended to depend from allowed claim 76.

Applicant(s): P. Bonutti  
Application No.: 09/925,551  
Examiner: V. Bui

Accordingly, Applicant respectfully submits that dependent claims 72, 73, and 77-90 are also allowable over McGuire.

For the reasons set forth below, Applicant respectfully submits that claims 91-95, and 97-108 are patentable over McGuire. The Examiner states that:

McGuire (Figs. 1, 4a-4b, 5-6; col 9, ll. 60-64) discloses autogenous bone or freeze-dried bone anchor/plug 25, suture 27, cutting tool 33 to cut out autogenous bone plug 25, elongate member/drill to form passages for suture 27 in bone plug 25. Allograft bone plug can be provided from a freeze-drying process.

Noticing that holes/passages 27 are formed by drilling through anchor/bone plug 25 (Col. 6, lines 34-36) and have a larger diameter than that of the suture (Fig. 4a-4b). Therefore, the suture of McGuire can slide freely through the passages drilled in the bone anchor/plug 25 as recited in the independent claim 71. In addition, notice that bone anchor/plug 25 secures first tissue (femur 14) and second tissue (tibia 12) and retains first tissue (femur 14) and second tissue (tibia 12) against relative movement relative to each other as recited in the independent claim 91 because anchor/plug 25 does not allow a separation/relative movement of the first tissue (femur 14) linearly away from second tissue (tibia 12).

McGuire relates to the field of arthroscopic surgery, particularly anterior cruciate ligament reconstruction. (Col. 1, lns. 18-20). The two major bones that meet at the knee joint are the tibia 12 and the femur 14, a bone tunnel 16 is drilled through each of these two bones. (Col. 2, lns. 17-19). The semitendinosus tendon 20 and/or gracilis 21 is extended between both of the bone plugs. (Col 6, lns. 57-58). Sutures are also used through the suture holes to attach the tendon to each of the bone plugs. (Col. 6, lns. 62-63).

The sutures may be pulled on to properly tension and locate the graft within the bone tunnels. (Col. 9, lns 25-26). The sutures may be pulled on to properly tension and locate the graft with the bone tunnels. (Col. 9, lines 25-26). Fixation of the graft can be accomplished with a headless cannulated interface screw. (Col. 9, lns. 30-31).

Claim 91 recites a method of retaining portions of first and second tissue elements in a patient's body against movement relative to each other. The method includes the step of freeze drying body tissue. The freeze dried body tissue engages at least one of the first and second tissue elements in the patient's body, securing the first and second body tissue elements together.

Applicant(s): P. Bonutti  
Application No.: 09/925,551  
Examiner: V. Bui

The first and second body tissue elements are secured together by transmitting force between the first and second tissue elements through the freeze dried body tissue, such that the first and second tissue elements are retained against movement relative to each other.

As noted above, McGuire discloses a composite graft for a reconstruction ligament in a knee. A knee is a hinged joint connecting the femur and the tibia. When the knee is moved in flexion or extension the tibia moves relative to the femur, rotating about a central axis of rotation. There is also a slight translational and twisting component in this motion. The knee is held together by four ligaments. A ligament is a structure in the knee that holds the bones together and helps to control joint movement or motion.

The role of the anterior cruciate ligament (ACL) is to hold the tibia tightly to the femur as the knee moves in flexion or extension. The ACL substantially prevents the lower tibia bone from migrating anteriorly from underneath the femur. The ACL also substantially prevents the lower tibia bone from rotating (twisting). The result is that an individual, such as an athlete, can rapidly turn, twist, and resume running at full speed without the knee collapsing.

The purpose of ACL reconstruction surgery is to repair a torn or damaged ACL, to tighten the knee, restoring stability to the knee. After ACL reconstruction surgery, the knee gradually returns to full flexibility and stability, allowing for full range of motion.

The composite graft of McGuire includes a pair of bone plugs with a tendon wrapped there around. The tendon can be secured to the bone plug with sutures. The bone plugs are inserted into the bone tunnels in the femur and tibia and affixed thereto, replacing the ACL. The purpose of replacing the ACL is to provide stability to the knee joint, allowing for a full range of motion in the knee. The replacement ACL allows relative movement between the femur and the tibia, allowing the tibia to rotate relative to the femur. The preventing of relative motion of the tibia relative to the femur is specifically taught against by McGuire and would defeat the underlying intended purpose of McGuire, which is to restore stability and full range of motion to the knee. As such, McGuire does not disclose using the bone plugs to the secure the femur to the tibia, preventing relative movement with respect to each other.

Additionally, claim 91 now recites that the first tissue is bone tissue and the second tissue

Applicant(s): P. Bonutti  
Application No.: 09/925,551  
Examiner: V. Bui

is soft tissue. McGuire discloses a graft coupling a first bone (femur) to a second bone (tibia).

Accordingly, Applicant submits that McGuire does not teach or suggest all of the elements of claim 91. In light of the foregoing, independent claim 91 is respectfully submitted to be patentable over McGuire. As claims 92-95 and 97-108 depend from claim 91, these dependent claims necessarily include all the elements of their respective base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over McGuire at least for the same reasons.

#### Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fee is believed to be due for this submission. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 782-A03-013-3).

Respectfully submitted,



Paul D. Bianco, Reg. # 43,500

Customer Number: 33771  
Paul D. Bianco  
FLEIT KAIN GIBBONS GUTMAN BONGINI & BIANCO  
601 Brickell Key Drive, Suite 404  
Miami, Florida 33131  
Tel: 305-931-9620; Fax: 305-931-9627  
e-mail: [pbianco@focusonip.com](mailto:pbianco@focusonip.com)